AMENDMENTS TO THE DRAWINGS

The attached one sheet of drawings include changes to Fig. 1. This sheet, which includes only one Figure, replaces the original sheet including only Fig. 1. In Fig. 1, the rectangular boxes have been given text labels in accordance with their descriptions in the specification. No new matter has been added.

Attachment: One Replacement Sheet
One Annotated Sheet Showing Changes

REMARKS

Certified copy of priority document

Applicant respectfully submits that the certified copy of the priority document was previously provided by the Applicant as mailed on April 8, 2004. Also, Private PAIR shows that the certified copy has been received by the USPTO.

Claim status

Claims 1-64 were pending in the case at the time of the current Office Action. Claims 1, 3-14, 16-17, 23, 28, 30, 32, 34-35, 38-40, 42-43, 45-47, 49, 55-57, 59-62, and 64 are currently amended herein. Claims 2, 18-22, 24-27, 29, 31, 33, 36-37, 41, 44, 48, 53, 58, and 63 are cancelled herein. Claims 1, 3-17, 23, 28, 30, 32, 34-35, 38-40, 42-43, 45-47, 49-52, 54-57, 59-62, and 64 are currently pending in the application.

Drawing rejections

In the current Office action, the drawings are objected to because the unlabeled rectangular boxes shown in Fig. 1 should both be provided with descriptive text.

Applicants respectfully traverse the foregoing objection in view of the above amended drawings and for reasons set forth hereafter.

The descriptive text has been added to Fig. 1 herein. No new matter has been added. Applicants respectfully request that the amended Figure be entered and that the objection be withdrawn.

Specification objections

In the current Office action, the Examiner is objecting to the ABSTRACT and is requiring a new ABSTRACT because it contains confusing language and/or terminology.

Applicants respectfully traverse the foregoing objection in view of the above amended drawings and for reasons set forth hereafter.

The ABSTRACT has been amended herein. No new matter has been added.

Applicants respectfully request that the amended ABSTRACT be entered and that the objection be withdrawn.

In the current Office action, the disclosure is objected to as failing to provide proper antecedent basis for the claimed subject matter and for minor informalities.

Applicants respectfully traverse the foregoing objection in view of the above amended paragraphs and claims and for reasons set forth hereafter.

The specification and claims have been amended herein to clean up any antecedent basis problems and to correct any minor informalities. No new matter has been added.

Applicants respectfully request that the amended paragraphs and claims be entered and that the objections be withdrawn.

Claim objections

In the current Office action, claim 1 is objected to because of informalities and for omitting essential elements, claim 19 is a substantial duplicate of claim 4, claims 20-21 are a substantial duplicate of claim 5, and claims 24-25 are a substantial duplicate of claim 6.

Applicants respectfully traverse the foregoing objection in view of the above amended claims and for reasons set forth hereafter.

Claims 19, 20-21, and 24-25 have been cancelled herein.

Applicants respectfully request that the amended claims be entered and that the objections be withdrawn.

Section 112 rejections

In the current Office action, claims 1-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

In the current Office action, claims 1-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and specification amendments and for reasons set forth hereafter.

The claims have been amended or cancelled herein to address the 35 U.S.C. 112 rejections. The explanation of the claimed invention under the next section herein addressing the 103 rejections clarifies the claimed invention in relation to the amended claims and is believed to address the 112 rejections.

For example, with respect to the strength of the stimulation pulse, it should be clear that the strength of the stimulation pulse depends on how long the control unit 26 keeps switch S1 closed (i.e., how much the reservoir capacitor 22 gets charged up). Therefore, it would be clear to one skilled in the art that the control unit adjusts the strength of the stimulation pulse by controlling how long switch S1 is closed. The determination of how long switch S1 should be closed is based on the monitoring of the stimulation outcome. Claim 1 as amended now clearly claims how the means for monitoring stimulation outcome is accomplished (i.e., detecting a drop in a voltage over time at the capacitance or a rise in a short-circuit current over time at the capacitance after delivery of the stimulation pulse, the drop in voltage or the rise in short-circuit current being representative of a characteristic drop in a myocardium impedance of the body tissue). Various threshold comparisons may be made, either on the detected voltage or current, time derivatives thereof, and/or standardized time derivatives thereof (see claims 9-11, for example). The comparisons indicate that stimulation was successful or not. This information is used by the control unit to increase (if stimulation was not successful) or possibly decrease (if stimulation was successful) the strength of a next stimulation pulse. This is clear from the specification and the claims.

As another example, with respect to claim 9, it would be clear to one skilled in the art that the detected voltage eorresponds to the detected voltage over time as referred to in claim 1, and not the derivative of the detected voltage with respect to time. Claim 10 addresses using the derivative of the detected voltage with respect to time.

Furthermore, the capacitance referred to in claim 1 is clearly stated in claim 1 as being at least one Helmholz capacitance, and in claim 2 as further comprising a coupling capacitor. The other capacitance talked about in the specification and the claims is the reservoir capacitor (energy storage means). It would be clear to one skilled in the art which of these capacitances are being talked about and when in the claims and specification.

Therefore, in view of at least the foregoing, it is respectfully submitted that rejections of claims 1-64 under 35 U.S.C. 112, first and second paragraphs, have been overcome.

Applicants respectfully request that the rejection of claims 1-64 under 35 U.S.C. 112, first and second paragraphs, be removed.

Section 103 rejections

In the current Office action, claims 1-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pons et al. (US 2002/0147477), hereinafter Pons, in view of Paul et al. (US 5,735,883), hereinafter Paul.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Independent claim 1 recites a device for electrostimulation of body tissue through a stimulation electrode, comprising:

energy storage means for providing electrical stimulation energy to the stimulation electrode from an energy source;

a first switch with which the energy storage means is switchably connected to the energy source for charging the energy storage means;

an electrode connection for connecting the stimulation electrode to the device for delivering electrical stimulation pulses to the body tissue;

a second switch with which the energy storage means is switchably connected to the electrode connection for the delivery of a stimulation pulse;

means for monitoring stimulation outcome;

a short-circuit switch with which the electrode connection, after delivery of the stimulation pulse, is switchably and at least indirectly connected to a ground potential such that, in the case of a connected and implanted electrode, a capacitance can be discharged by way of the body tissue, wherein the capacitance includes at least one Helmholtz capacitance produced on the surface of the stimulation electrode in conjunction with surrounding body fluid or the body tissue; and

a control unit which is connected to at least the first switch, the second switch, and the short-circuit switch for switching the respective switches and which is adapted to separate the electrode connection from the energy storage means after delivery of the stimulation pulse and at least indirectly connect the electrode connection to the ground potential;

wherein the means for monitoring stimulation outcome, at least after delivery of a stimulation pulse, is connected to the electrode connection and is adapted to detect a drop in a voltage over time at the capacitance or a rise in a short-circuit current over time at the capacitance after delivery of the stimulation pulse, said drop in voltage or said rise in short-circuit current being representative of a characteristic drop in a myocardium impedance of said body tissue.

It is respectfully submitted neither Pons, Paul, nor the combination thereof teach or suggest the invention of independent claim 1. In particular, Pons and Paul do not teach or suggest a means for monitoring stimulation outcome, at least after delivery of a stimulation pulse, that is connected to the electrode connection and is adapted to detect a drop in a voltage over time at the capacitance or a rise in a short-circuit current over time at the capacitance after delivery of the stimulation pulse, the drop in voltage or rise in short-circuit current being representative of a characteristic drop in myocardium impedance.

The claimed invention is based on the fact that the impedance of the myocardium shows a drop if a stimulation pulse was strong enough to cause excitation of the myocardium and thus has led to successful capture. Such excitation of the myocardium is followed by a contraction of

a stimulated heart chamber. Such a contraction of a stimulated heart chamber can be detected by measuring impedance since blood has a lower impedance than the myocardium so that the impedance in a heart chamber increases when the heart chamber contracts. However, this kind of impedance measurement as known, for example, from Paul is different from measuring the impedance of the myocardium, since the impedance measured by the arrangement as known from Paul mainly depends on the blood impedance.

With the claimed invention, a short term drop in the impedance of the myocardium itself is detected. In order to measure such short term drop of impedance, a current or a voltage source is used which is readily available immediately after delivery of the stimulation pulse. According to the claimed invention, a capacitor that is in the short cut circuit (from the myocardium to ground potential) during autoshort after delivery of a stimulation pulse is used as a current or a voltage source. The short term drop of myocardial impedance is detected by evaluating a time course of a voltage or a current over a capacitance in the short cut circuit. This capacitance can be a coupling capacitor, a Helmholz capacitance, or a combination of both, or any other capacitance in the short cut circuit as would be apparent to one skilled in the art. One skilled in the art knows that a load impedance can be determined by either analyzing a time course of a voltage when discharging a capacitor into a load, or a time course of a current, since it is the slope of the voltage or the current that characteristically depends on the load (impedance of the myocardium).

Pons does not disclose how a means for monitoring stimulation outcome is able to determine, after delivery of stimulation, whether stimulation was effective or if, on the contrary, there was a loss of capture. However, Applicants respectfully submit that these lacking features in Pons are not taught or suggested by Paul since the device according to Paul is not capable of measuring a short term impedance drop in the myocardium impedance. Instead, the device of Paul is adapted to determine mechanical contraction of a heart chamber by measuring the change of impedance due to the blood volume displaced out of the heart chamber during contraction.

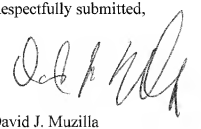
The device of Paul measures the change of impedance do to mechanical volume change caused by a captured stimulation pulse (see col. 8, lines 13 ff, "After the pacing pulse 102, the impedance increases as the heart contracts…", col. 8, lines 22 and 23). According to Paul, any

change of the myocardial impedance is considered to be an error (see col. 7, line 57 to col. 8, line 12).

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 is not unpatentable over Pons in view of Paul, and it is respectfully submitted that independent claim 1 defines allowable subject matter. Also, since claims 3-17, 23, 28, 30, 32, 34-35, 38-40, 42-43, 45-47, 49-52, 54-57, 59-62, and 64 depend either directly or indirectly from claim 1, it is respectfully submitted that claims 3-17, 23, 28, 30, 32, 34-35, 38-40, 42-43, 45-47, 49-52, 54-57, 59-62, and 64 define allowable subject matter as well. Applicants respectfully request that the rejection of claims 1-64 under 35 U.S.C. 103(a) be removed.

Accordingly, the applicant respectfully requests reconsideration of the rejections and objections based on at least the foregoing. After such reconsideration, it is urged that allowance of all pending claims will be in order.

Respectfully submitted,



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